UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

LAURA KILLOUGH, Individually and as Administrator of the Estate of Kevin Killough, M.D.,	)	CASE NO.:
	)	
	)	Judge:
Plaintiff,	)	
	)	
v.	)	
	)	
MEDTRONIC, INC.; MEDTRONIC MINIMED, INC.; MINIMED DISTRIBUTION CORP.; and MEDTRONIC USA, INC.,	)	**PLAINTIFF'S ORIGINAL COMPLAINT**
	)	
Defendants.	)	

Plaintiff, Laura Killough, Individually and as Administrator of the Estate of Kevin Killough, M.D., by and through the undersigned counsel, brings this Complaint against Defendants, Medtronic, Inc., Medtronic MiniMed, Inc., MiniMed Distribution Corp., and Medtronic USA, Inc. (hereinafter collectively referred to as "Defendants"), and alleges as follows:

INTRODUCTION

1. Dr. Kevin Killough was a Type 1 diabetic who used a Medtronic insulin pump and a Medtronic MiniMed Silhouette Paradigm Infusion Set for insulin administration.

2. On December 30, 2017, Dr. Kevin Killough died because the subject Medtronic MiniMed Silhouette Paradigm Infusion Set (the "Defective Product") malfunctioned, which resulted in Dr. Killough receiving a fatal dose of insulin.

PARTIES, JURISDICTION, AND VENUE

3. This Court properly has diversity jurisdiction of this action pursuant to 28 U.S.C. § 1332(a), as the matter in controversy exceeds the sum value of $75,000.00, exclusive of interest and costs, and it is between citizens/entities of different states.

4. Venue in this action properly lies in the Toledo Division of the Northern District of Ohio pursuant to 28 U.S.C. §§ 1391 (a) and (c), as a substantial number of the events, actions, or omissions giving rise to Plaintiff's claims occurred in Lima, Allen County, Ohio.

5. At all times relevant, Plaintiff and her deceased husband, Kevin Killough, M.D., were residents of Allen County, Ohio.

6. Plaintiff Laura Killough is the duly appointed Administrator of the Estate of Kevin Killough, M.D., deceased, and files this Complaint pursuant to Ohio's survivorship statute, R.C. § 2305.21, and Ohio's wrongful death statute, R.C. 2125.01, *et seq.*

7. Defendant Medtronic, Inc. is a foreign corporation organized under the laws of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. At all times relevant, Medtronic, Inc., regularly conducted business in Ohio and derived substantial revenue from goods used in Ohio.

8. Defendant Medtronic MiniMed, Inc. is a foreign corporation organized under the laws of Delaware, with its principal place of business at 18000 Devonshire Street, Northridge, California 91325. At all times relevant, Medtronic MiniMed, Inc., regularly conducted business in Ohio and derived substantial revenue from goods used in Ohio.

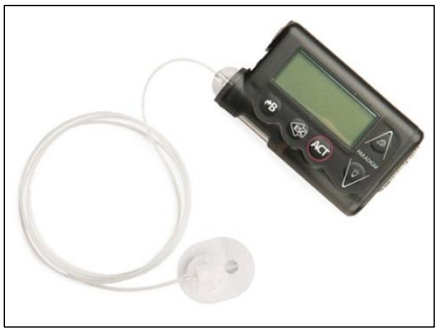
9. Defendant MiniMed Distribution Corp. is a foreign corporation organized under the laws of Delaware, with its principal place of business at 18000 Devonshire Street, Northridge, California 91325. At all times relevant, MiniMed Distribution Corp., regularly conducted business in Ohio and derived substantial revenue from goods used in Ohio.

10. Defendant Medtronic USA, Inc. is a foreign corporation organized under the laws of Minnesota, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432. At all times relevant, Medtronic USA, Inc., regularly conducted business in Ohio and derived substantial revenue from goods used in Ohio.

11. Defendants sold the Defective Product to Dr. Killough in Ohio and shipped the Defective Product to Dr. Killough in Ohio.

FACTUAL ALLEGATIONS

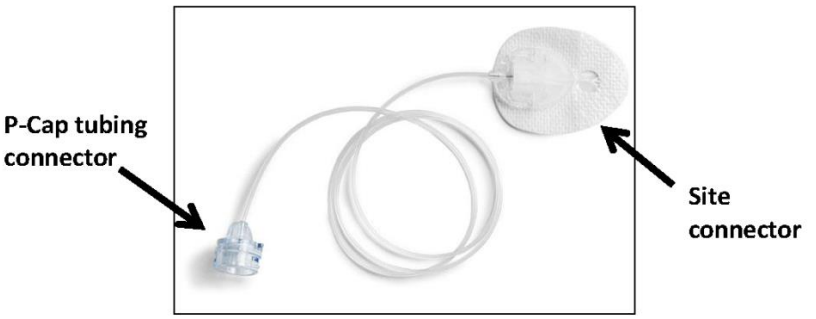
12. Diabetic patients use insulin pumps (pictured below) to help regulate their blood sugar. Insulin pumps are small portable electronic devices that hold a small bottle of insulin, called the insulin reservoir. An insulin pump is used in conjunction with a disposable "infusion set," which is a thin plastic tube that connects the insulin pump to the patient's body.



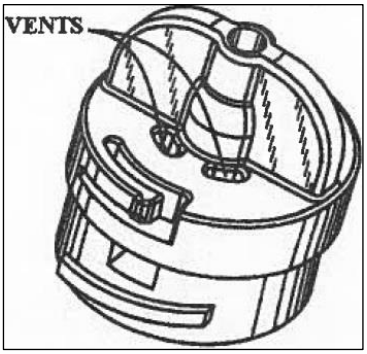
13. To deliver insulin, a plunger inside the insulin pump mechanically forces insulin from the insulin reservoir, through the plastic tubing, and into the patient's body.

14. When functioning properly, insulin pumps deliver a designated dose of insulin to the diabetic patient over a prolonged period of time.

15. The MiniMed Silhouette Paradigm Infusion Set consists of a plastic tube with a "P-Cap tubing connector" at one end (which connects the plastic tube to the insulin reservoir), and a "site connector" at the other end (which has a small plastic needle that is inserted into the patient's body).

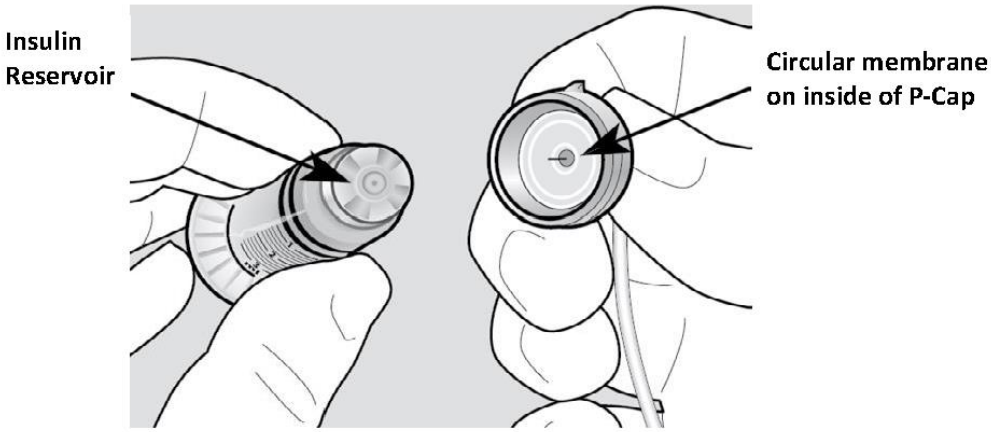


16. The P-Cap tubing connector (sometimes referred to herein as the "p-cap") contains four small vents that allow air to flow in and out of the insulin reservoir. This air flow keeps the air pressure inside the insulin reservoir consistent with the external air pressure. The picture to the right shows two of the four vents in the p-cap.



17. The vents are covered by a circular membrane located on the inside of the p-cap. The topside of the membrane (the part that touches the vents) is made of polytetrafluoroethylene (PTFE), which is hydrophobic, and thus prevents liquid from entering the vents. The underside of the circular membrane (the part that touches the insulin reservoir) is made of polyester and is hydrophilic.

18. The p-cap is connected to the top of the insulin reservoir. The insulin reservoir is then placed into the insulin pump.



19. If insulin or other liquids contact the underside of the p-cap membrane, the vents can become blocked.

20. The infusion set must be changed every few days. After a new infusion set is connected to the insulin reservoir, insulin must be pumped all the way through the plastic tubing. This is known as priming the pump.

21. The ability of the p-cap to equalize the pressure within the insulin reservoir is critical when the user is priming the pump. If vents on the p-cap are blocked (e.g., from insulin or other liquids contacting the underside of the p-cap membrane), priming the pump will cause an increase in pressure inside the reservoir. This increase in pressure will force insulin out of the reservoir, through the plastic tubing of the infusion set, and into the patient – until pressure equilibrium is achieved. Thus, a pressure imbalance due to clogged vents can cause too much insulin to be delivered to the patient.

22. The Medtronic MiniMed Silhouette Paradigm Infusion Set, including the Defective Product, is and was defective and unreasonably dangerous because when used as intended and in a reasonably foreseeable manner, the p-cap vents can become blocked, resulting in the over-delivery of insulin.

23. As a result of the defective condition of the Defective Product as described herein, Dr. Killough received a lethal dose of insulin from the Defective Product after he went to sleep at his home in Allen County, Ohio the night of December 29, 2017, which resulted in extreme hypoglycemia, conscious pain and suffering, and death.

24. Dr. Killough, who had been home alone while his family was traveling for the holidays, was found deceased on December 30, 2017.

25. Dr. Killough's official cause of death as determined by the Allen County, Ohio Coroner was cardio-pulmonary arrest due to, or as a consequence of, a sudden hypoglycemic event.

26. Defendants knew about the defective condition of the Medtronic MiniMed Silhouette Paradigm Infusion Sets for many years prior to Dr. Killough's death, but failed to fix the problem or adequately warn Dr. Killough or his healthcare providers.

27. Defendants' conduct described herein exhibited a conscious and flagrant disregard for the rights and safety of persons who might be harmed by the Defective Product, including Dr. Killough.

COUNT I
DESIGN DEFECT (R.C. § 2307.75)

28. Plaintiff incorporates paragraphs 1-27 as if fully stated herein.

29. This survivorship claim is based upon a design defect and is being brought against Defendants pursuant to Ohio Revised Code § 2307.75 and § 2305.21.

30. Defendants designed, manufactured, marketed, and sold the Medtronic MiniMed Silhouette Paradigm Infusion Sets, including the Defective Product.

31. Defendants are the manufacturer of the Defective Product pursuant to R.C. § 2307.71(A)(9).

32. The Defective Product was defective and unreasonably dangerous in design at the time it left the control of the Defendants because the foreseeable risks associated with its design as described herein exceeded the benefits associated with its design.

33. Dr. Killough used the Defective Product for its intended purpose and in a reasonably foreseeable manner.

34. Defendants sold the Defective Product in a defective and unreasonably dangerous condition such that, when it was used as intended and in a reasonably foreseeable manner by Dr. Killough, the p-cap vents became blocked which resulted in the over-delivery of insulin to Dr. Killough, causing Dr. Killough to suffer conscious pain and suffering, permanent injuries, and death.

35. The Defective Product was not unavoidably unsafe.

36. Defendants failed to adequately warn and instruct Dr. Killough and his healthcare providers about the defective condition of the Defective Product.

37. The defective condition of the Defective Product as described herein could have been eliminated without substantially compromising the product's usefulness or desirability.

38. At the time the Defective Product left the control of Defendants, a practical and technically feasible alternative design was available, and such design would have prevented Dr. Killough's death without substantially impairing the usefulness or intended purpose of the Defective Product (e.g., utilizing a membrane that would not block the vents if it came into contact with insulin or another liquid).

39. The Defective Product failed to perform as an ordinary consumer would expect when it was used in a reasonably foreseeable manner.

40. The design defect of the Defective Product as described herein directly and proximately caused Dr. Killough to suffer conscious pain and suffering, permanent injuries, and death.

WHEREFORE, Plaintiff demands judgment against all Defendants, jointly and severally, for compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00) for Kevin Killough M.D.'s injuries and conscious pain and suffering prior to his death, as well as costs, pre-judgment and post-judgment interest, and all other relief this Honorable Court finds just and equitable.

WHEREFORE FURTHER, Plaintiff demands punitive exemplary damages against Defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00) that will adequately punish and deter the acts and admissions alleged herein, reasonable attorneys' fees, costs of suit, and any other relief this Honorable Court finds just and equitable.

COUNT II
INADEQUATE WARNING AND INSTRUCTION (R.C. § 2307.76)

41. Plaintiff incorporates paragraphs 1-27 as if fully stated herein.

42. This survivorship claim is based upon a defect due to inadequate warning and instruction and is being brought against Defendants pursuant to Ohio Revised Code § 2307.76 and § 2305.21.

43. Defendants designed, manufactured, marketed, and sold the Medtronic MiniMed Silhouette Paradigm Infusion Sets, including the Defective Product.

44. Defendants are the manufacturer of the Defective Product pursuant to R.C. § 2307.71(A)(9).

45. The Defective Product was defective and unreasonably dangerous at the time it left the control of the Defendants because the foreseeable risks associated with its design as described herein exceeded the benefits associated with its design, and it did not contain warnings or instructions that would render it reasonably safe.

46. Dr. Killough used the Defective Product for its intended purpose and in a reasonably foreseeable manner.

47. Defendants sold the Defective Product in a defective and unreasonably dangerous condition such that, when it was used as intended and in a reasonably foreseeable manner by Dr. Killough, the p-cap vents became blocked which resulted in the over-delivery of insulin to Dr. Killough, causing Dr. Killough to suffer conscious pain and suffering, permanent injuries, and death.

48. The Defective Product was defective and unreasonably dangerous due to inadequate warning and instruction at the time of marketing because:

a. At the time the Defective Product left the control of Defendants, Defendants knew, or in the exercise of reasonable care, should have known about the risks of the p-cap vents becoming blocked resulting in the over-delivery of insulin; and

b. At the time the Defective Product left the control of Defendants, Defendants failed to provide the warning and instruction that a manufacturer exercising reasonable care would have provided concerning the risks of the p-cap vents becoming blocked resulting in the over-delivery of insulin, in light of the likelihood that the Defective Product would cause serious injury and/or death.

49. The Defective Product was defective due to inadequate post-marketing warning and instruction because:

a. After the Defective Product left the control of Defendants, Defendants knew, or in the exercise of reasonable care, should have known about the risks of the p-cap vents becoming blocked resulting in the over-delivery of insulin; and

b. After the Defective Product left the control of Defendants, Defendants failed to provide the post-marketing warning and instruction that a manufacturer exercising reasonable care would have provided concerning the risks of the p-cap vents becoming blocked resulting in the over-delivery of insulin, in light of the likelihood that the Defective Product would cause serious injury and/or death.

50. The risks of failure of the Defective Product as described herein were not open and obvious risks and were not risks that are matters of common knowledge.

51. Defendants failed to adequately warn and instruct Dr. Killough and his healthcare providers about the defective condition of the Defective Product.

52. Had Dr. Killough received adequate warning or instruction as to the risks associated with using the Defective Product as described herein, Dr. Killough would not have used the product.

53. The Defective Product was defective due to inadequate warning and instruction as described herein and said inadequate warning and instruction directly and proximately caused Dr. Killough to suffer conscious pain and suffering, permanent injuries, and death.

WHEREFORE, Plaintiff demands judgment against all Defendants, jointly and severally, for compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00) for Kevin Killough M.D.'s injuries and conscious pain and suffering prior to his death, as well as costs, pre-judgment and post-judgment interest, and all other relief this Honorable Court finds just and equitable.

WHEREFORE FURTHER, Plaintiff demands punitive exemplary damages against Defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00) that will adequately punish and deter the acts and admissions alleged herein, reasonable attorneys' fees, costs of suit, and any other relief this Honorable Court finds just and equitable.

COUNT III
MANUFACTURING DEFECT (R.C. § 2307.74)

54. Plaintiff incorporates paragraphs 1-27 as if fully stated herein.

55. This survivorship claim is based upon a manufacturing defect and is being brought against Defendants pursuant to Ohio Revised Code § 2307.74 and § 2305.21.

56. Defendants are the manufacturer of the Defective Product pursuant to R.C. § 2307.71(A)(9).

57. The Defective Product was defective and unreasonably dangerous in manufacture at the time it left the control of the Defendants because the p-cap vents could become blocked resulting in the over-delivery of insulin, which deviated in a material way from the design specifications and performance standards of Defendants.

58. Dr. Killough used the Defective Product for its intended purpose and in a reasonably foreseeable manner.

59. Defendants sold the Defective Product in a defective and unreasonably dangerous condition such that, when it was used as intended and in a reasonably foreseeable manner by Dr. Killough, the p-cap vents became blocked which resulted in the over-delivery of insulin to Dr. Killough, causing Dr. Killough to suffer conscious pain and suffering, permanent injuries, and death.

60. The manufacturing defect in the Defective Product as described herein directly and proximately caused Dr. Killough to suffer conscious pain and suffering, permanent injuries, and death.

WHEREFORE, Plaintiff demands judgment against all Defendants, jointly and severally, for compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00) for Kevin Killough M.D.'s injuries and conscious pain and suffering prior to his death, as well as costs, pre-judgment and post-judgment interest, and all other relief this Honorable Court finds just and equitable.

WHEREFORE FURTHER, Plaintiff demands punitive exemplary damages against Defendants in an amount in excess of Seventy-Five Thousand Dollars ($75,000.00) that will

adequately punish and deter the acts and admissions alleged herein, reasonable attorneys' fees, costs of suit, and any other relief this Honorable Court finds just and equitable.

COUNT IV
WRONGFUL DEATH

61. Plaintiff incorporates all other paragraphs as if fully stated herein.

62. Plaintiff Laura Killough is the duly appointed Administrator of the Estate of Kevin Killough, M.D., Deceased, and brings this Fourth Cause of Action pursuant to Ohio's wrongful death statute, R.C. §§ 2125.01, *et seq.*

63. At all times relevant, Plaintiff Laura Killough, was the spouse of Dr. Kevin Killough.

64. The defective and unreasonably dangerous condition of the Defective Product as described herein, due to design defect (R.C. § 2307.75) and/or inadequate warning and instruction (R.C. § 2307.76) and/or manufacturing defect (R.C. § 2307.74), proximately caused the wrongful death of Dr. Killough.

65. As a direct and proximate result of the defective and unreasonably dangerous condition of the Defective Product as described herein, Dr. Killough's next of kin, including Dr. Killough's spouse Laura Killough and their children, suffered damages as set forth in Ohio's wrongful death statute, R.C. § 2125.02, including mental anguish and the loss of support, services, society, and prospective inheritances.

WHEREFORE, Plaintiff demands judgment against all Defendants, jointly and severally, for compensatory damages in excess of Seventy-Five Thousand Dollars ($75,000.00) for all damages suffered by Kevin Killough, M.D.'s next of kin recoverable under Ohio's wrongful death statute, R.C. § 2125.02, including mental anguish and loss of support, services,

society, and prospective inheritances, as well as costs, pre-judgment and post-judgment interest, and all other relief this Honorable Court finds just and equitable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

(a) Awarding compensatory damages to Plaintiff in an amount to be determined at trial, but which is in excess of Seventy-Five Thousand Dollars ($75,000.00) exclusive of interest, costs, and attorneys' fees;

(b) Awarding punitive damages;

(c) Awarding pre-judgment and post-judgment interest to Plaintiff;

(d) Awarding the taxable costs and expenses of litigation to Plaintiff;

(e) Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law; and

(f) Granting all such other relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury on all issues so triable as a matter of right.

Dated November 6, 2018

Respectfully submitted,

s/ *Nicholas A. DiCello*
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